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09/936,921	09/24/2001	Didier Raoult		3015

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Oliff & Berridge
PO Box 19928
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10/31/2007

EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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10/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/936,921	RAOULT ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Muller, Schoedon and Drancourt.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 10, 11, 15, 25, 29-32 and 35-~~69~~⁶⁹ is/are pending in the application.
- 4a) Of the above claim(s) 46-62, 64 and 65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 10, 11, 15, 25, 29-32, 35-39, 41-42, 63 and 66-~~69~~⁶⁹ is/are rejected.
- 7) ☒ Claim(s) 40, 43-45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's response filed on 2/5/07 , 5/17/07 and 7/19/07 is acknowledged.

Status of claims

2. New claims 35-69 have been added.

Claims 1,10,11,15,25,29-32 and 35-69 are pending.

Newly submitted claims 46-62, 64 and 65 are drawn to a process of culturing

Tropheryma whippelii . As these claims are directed to a method of making a product , they will be rejoined when the product claims are found allowable. Therefore, claims 46-62, 64 and 65 are withdrawn from consideration as drawn to a non elected invention.

Claims 1,10, 11, 15, 25, 29 , 30-32, 35-45, 63 and 66-69 are under examination.

New Claim Rejections - 35 USC 112, first paragraph maintained

3. The written description and enablement rejections of claims 1, 10, 11, 15, 25 , 29, 30, 31, 32 , and newly added claims 35-39, 41-42, 63 and 66-69 under 35 USC 112, first paragraph are maintained for the same reasons as set forth in the previous office action.

Claim 1 is drawn a culture comprising a bacterium responsible for Whipple's disease, said bacterium being isolated and established in culture such that the bacterium reproducibly multiplies over time, wherein the bacterium is of the same species as the *Tropheryma whippelii* bacterium strain deposited in the CNCM of the Institute Pasteur under Deposit No. 1-2202, Claim 10 is drawn to an antigen isolated from a *Tropheryma whippelii* bacterium, wherein said antigen is a protein of 200 kD determined by polyacrylamide gel electrophoresis using the Western blotting technique, which reacted with specific monoclonal antibody directed against the bacterium *Tropheryma whippelii* responsible for Whipple's disease or an antigen of said bacterium, said antibody being produced by a hybridoma deposited in the CNCM of the Institute Pasteur under the Deposit No. 1-2411. Claims 11 and 15 are drawn to a method for the in vitro diagnosis of diseases associated with infections caused by *Tropheryma whippelii*, comprising contacting serum or any other biological fluid of a patient with a culture according to claim 1 or a *Tropheryma whippelii* bacterium obtained from said culture, and detecting an immunological reaction , said method comprising depositing a solution containing said *Tropheryma whippelii* bacterium in or on a solid support; introducing serum or any other biological fluid into or onto said support, introducing a solution of a labeled antibody specific for a human immunoglobulin, which recognizes said bacterium and detecting an immunological reaction. Claims 25 and 29 are drawn to a method for the in vitro diagnosis of diseases associated with infections caused by *Tropheryma whippelii*, comprising contacting serum or any other biological fluid of a patient with an antigen according to claim 10 and detecting an immunological reaction , said method comprising depositing a solution containing said *Tropheryma whippelii* bacterium in or on a solid support; introducing serum or any other biological fluid into or onto said support, introducing a solution of a labeled antibody specific for a human immunoglobulin, which recognizes said bacterium and detecting an immunological reaction, wherein said culture is not a cell culture in monocyte cells (claim 30), a cell culture in immortalized cells (claim 31) , said immortalized cells are fibroblast cells (claim 32).

The specification teaches that the novel TWIST-Marseille strain *Tropheryma whippelii* was cultivated on embryonic human fibroblasts continuously and deposited in the

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CNCM under deposit no 1-2202. However, it appears that more than one strain of bacteria and heterogeneity exists among Whipple's disease associated bacteria. Therefore, it is expected that different strains would have different sequences and different proteins as known in the art of bacteriology. Given that only TWIST-Marseille strain *Tropheryma whippelii* is cultured, given that there are different strains exists, the structure and function of other unknown/uncharacterized strains as claimed do not have written description support.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Id.* At 1567, 43 USPQ2d at 1405. The court also stated that a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. *Id.* At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.*

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.* The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002).

The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristicsi.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.'" *Id.* At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs *per se*, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

Thus, the instant specification may provide an adequate written description of the strain *Twist-Marseille Tropheryma whippelii* CNCM 1-2202, *per Lilly* by structurally describing a representative number of strains /species of *Tropheryma whippelii* that these species, responsible for Whipple's disease have been continuously cultured or by describing "structural features common to the members of the genus, which features constitute a substantial portion

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of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe claimed bacteria that are isolated and established in culture which are responsible for whipple's disease which are of the same species as *Tropheryma whippelii* Twist-Marseille CNCM 1-2202 or antigen produced from various species of *Tropheryma whippelii* required to practice the claims 1 10, 11, 15, 25, 29, 30, 31, 32 in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of any other species/strains *Tropheryma whippelii* nor does the specification provide any partial structure of such species/strains, nor any physical or chemical characteristics of the *Tropheryma whippelii* nor any functional characteristics coupled with a known or disclosed correlation between structure and function. Although the specification discloses a *Tropheryma whippelii* species CNCM, this does not provide a description of other species/strains of *Tropheryma whippelii*, that are responsible for whipple's disease, which claimed bacterium or antigen responsible for whipple's disease in culture, capable of diagnosing Whipple's disease associated diseases that would satisfy the standard set out in Enzo.

The specification also fails to disclose claimed bacteria that are isolated and established in culture which are responsible for whipple's disease which are of the same species as *Tropheryma whippelii* Twist-Marseille CNCM 1-2202 by the test set out in Lilly. The specification describes only a single *Tropheryma whippelii* species CNCM and an antigen isolated therefrom. Therefore, it necessarily fails to describe a "representative number" of such species/strains *Tropheryma whippelii* and antigens. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Thus, the specification does not provide an adequate written description of the *Tropheryma whippelii* species/strains or antigen that is required to practice the claimed invention. Since the specification fails to adequately describe the strains and antigen that are capable of functioning as claimed it also fails to adequately describe the claimed methods.

Applicant argues (2/5/07) that claim 1 is not directed to a new genetic material, but is instead directed to a culture comprising a culture medium and a known bacterium responsible for Whipple's disease and therefore, the subject matter of *Eli Lilly and Enzo* as discussed in the written description is not correct.

Applicants' arguments have been fully considered but they are not deemed to be persuasive because claim 1 is drawn to a product bacterium which consists of DNA. Therefore, the comparison of the subject matter of the *Eli Lilly and Enzo* to claim 1 is appropriate and proper.

Applicant argues that various species of *T. Whippelii* are known and applicant is not claiming the bacteria but the culture. Therefore, claim 1 and the dependent claims 10, 10, 11, 15, 25, 29, 30, 31 and 32 should not have been rejected.

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Applicants' arguments have been fully considered but they are not deemed to be persuasive because as applicant correctly pointed that various species are known in the art. However, the issue here is whether the specification provided support for all the cultures comprising diverse species of *T.whippelii* or not. The specification provides support only for the culture comprising *Tropheryma whippelii* bacterium strain deposited in the CNCM of the Institute Pasteur under Deposit No. 1-2202 . Therefore, claim 1 and the dependent claims 10, 10, 11, 15, 25 , 29, 30, 31, 32 ,35-39, 41-42, 63 and 66- 67 are not supported by the current specification for the culture comprising diverse species of *T.whippelii*.

Applicant argues that the doubling time , growth etc have been taught in the specification, therefore, these claims are enabled.

Applicants' arguments have been fully considered but they are not deemed to be persuasive because applicant is claiming the culture comprising the bacterium , which is a product , however, growth, doubling time etc are the properties of the bacterial strain deposited in the CNCM of the Institute Pasteur under Deposit No. 1-2202. Please note claims 43-45, drawn to culture, CNCM of the Institute Pasteur under Deposit No. 1-2202 are not included in this rejection. Since the claims do not provide support for the broadly claimed culture, the claims stand rejected under enablement rejection for the reasons set forth in the written description rejection as discussed above.

With respect to the antigen-related claims, Applicant argues that one of ordinary skill in the art would have understood that every bacterium that is isolated and established in culture is also an antigen source. The present disclosure also describes use of the bacterium isolated and established in the culture of claim 1 as an antigen source, and identifies as exemplary antigens proteins selected from those with molecular weights of about 10, 20, 35, 50, 60, 80, 100, 120, 150, 170 and 200 kD determined by polyacrylamide gel electrophoresis.

Applicants' arguments have been fully considered but they are not deemed to be persuasive because each antigen obtained from diverse species of *T.whippelii* is *different and distinct* . Given that only TWIST-Marseille strain *Tropheryma whippelii* is cultured, given that there are different strains exists, the structure and function of other unknown/uncharacterized antigens as claimed do not have support.

Claim Rejections - 35 USC 102 maintained

4. The rejections of claims ¹~~5~~ and newly added claims 68-69 under 35 U.S.C. 102(b) as being anticipated by Schoedon et al 1997 is maintained for the same reasons as set forth in the previous office action.

Schoedon et al disclose a culture comprising isolation of *Tropheryma whippelii* bacterium (see Journal Infectious diseases, 176; 672-677) responsible for Whipple's disease (see abstract) from biopsy material obtained from a patient. The bacterium is cultured in medium containing (see figure 1) deactivated mononuclear phagocytes (see page 673, right column, under inoculation of cultures) and this bacteria has been expanded in a large volume of cells SigM5 in growth medium (see page 673, right column) thus appears to be the same species as deposited under CNCM of the Institute Pasteur under Deposit No1-2202 and thus read on claim 1.

Applicant argues that Schoedon teaches a culture comprising a cell medium of monoblast from the cell line SigM5, which is derived from bone marrow. As is known to one of ordinary skill in the art, immortalized cell lines derived from monoblast and monocytes have a very short doubling time. Therefore, the art does not teach the invention as claimed.

Applicants' arguments have been fully considered but they are not deemed to be persuasive because the art disclose a culture comprising the bacterium. However, the bacterium can reproducibly and detectably multiply over time in the culture medium for at least 72 days is considered as inherent property of the bacterial culture. Since the Office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

5. The rejection of claims 1, 30, 31 and newly added claims 68-69 under 35 U.S.C. 102(b) as being anticipated by Muller et al 1999 GASTROENTEROLOGY. Vol, 116, No. 4. Part 2, Abstract 910, 1999. (Abstract only) is maintained as for the same reasons as set forth in the previous office action.

The prior art discloses *T. whippelii* replicate in IL4 treated monocytic U937 cell line (see abstract) and thus the bacteria multiply over the time as in the claimed invention. Since isolated bacteria is cultured, these claims do not distinguish the bacterium from the prior art as the art disclosed the same species *Tropheryma whippelii*. The prior art anticipated the claimed invention.

Applicant argues that Muller was published less than one year before the effective U.S. filing date of the present application (and indeed after the earliest priority date for this application), and thus is not prior art to the present application under 35 U.S.C. § 102(b).

Applicants' arguments have been fully considered but they are not deemed to be persuasive because there are no translated copies of the priority documents in the record to accord the priority before the publication date of Muller et al 1999. Therefore, the rejection is maintained.

6. The rejection of claims 1, 30, 31 and newly added claims 68-69 under 35 U.S.C. 102(b) as being anticipated by Drancourt 1999 Presse Medicale, Vol. 2: No. 8, February 27, 1999, pp. 435-439 (See translated article) is maintained as for the same reasons as set forth in the previous office action.

The prior art discloses *T. whipplei* is isolated from two heart valves sampled from two patients, deactivated by a combination of dexamethasone, interleukin-4 (IL-4) and IL10 (see Table 1) and bacteria was cultivated or propagated in human cell line, monoblast SigM5 (see page 8, bottom of the page) and thus the bacteria multiply over the time. This cell line grows continuously in cell culture as SigM5 is an immortalized cell line and it is not primary human monocytes and thus meets the limitations of claim 30 and 31. Since, the bacteria isolated and propagated in the culture it read on claims because these claims do not distinguish the bacterium from the prior art as the art disclosed the same *Tropheryma whippelii*. The prior art anticipated the claimed invention.

Applicant argues that as previously discussed and set forth in the Declaration of Drancourt article, filed on September 9, 2005, it provides a summary of various articles concerning *Tropheryma whippelii*. It does not set forth the results of any additional experimentation. In particular, the only article relating to cultivation of *Tropheryma whippelii* mentioned in Drancourt, Reference No. 13, is the Schoedon reference discussed above.

Applicants' arguments have been fully considered but they are not deemed to be persuasive because the article sets forth that *T. whippelii* was isolated from two heart valves sampled from two patients, deactivated by a combination of dexamethasone, interleukin-4 (IL-4) and IL10 (see Table 1) and bacteria was cultivated or propagated in human cell line. This read on the product culture as claimed in claim 1. Further, the limitation "bacterium can reproducibly and detectably multiply over time in the culture medium for at least 72 days" etc are considered the inherent properties of the bacterial culture. Since the Office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the

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burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Claim Rejections - 35 USC § 103 maintained

7. The rejection of claims 1, 11, 15, 25 and 29 –32 and 35-42 , 63 and 66-69 under 35 U.S.C. 103(a) as being unpatentable over Muller or Schoedon or Drancourt in view of Kent (abstract only, ARCH.PATHOL.LAB.MED 1980, 104 (10) 544-547 and Harlow and Lane 1986, Cold Spring Harbor Laboratory 1988, (chapters 14/5/6) is maintained as for the same reasons as set forth in the previous office action.

Muller or Schoedon or Drancourt as stated above teach an isolated *Tropheryma whippelii* bacterium . However, the prior art does not teach an antigen of said bacterium is used in a method of diagnosis comprising contacting the serum or any other biological fluid with bacteria or antigen on a solid support and detecting the immunological reaction.

Ken teaches a method of diagnosing whipple's disease by immunofluorescence whereas Harlow and Lane teach several immunoassays for detecting antibodies in a sample. These immunoassays are listed in Table 14.1 including the method for detecting antibody (see pages 560-561, 563). The method comprises contacting the antigen on a solid support with the test solution (i.e., serum, biological fluid etc) and detecting the antibody and antigen reaction (immunological reaction) using labeled secondary reagent.

It would have been prima facie obvious to one of ordinary skill in the art at the time invention was made to use the readily available bacteria in a method to diagnose whipple's disease because the prior art teaches how to grow bacteria and immunoassays using said bacteria as an antigen. Therefore, an artisan of ordinary skill would have been motivated to use *Tropheryma whippelii* bacterium in an immunoassay for the in vitro diagnosis of diseases associated with infections caused by *Tropheryma whippelii* because Drancourt 1999 clearly suggests that isolation of *Tropheryma whippelii* opens the way to the production of antigen for immunological diagnosis (see page 9 of Drancourt 1999). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to culture *Tropheryma whippelii* bacterium in an immortalized cell lines such as fibroblasts as taught by Muller et al 1999 or Drancourt 1999 in a routinely used immunoassay in a method for detecting antibodies as taught by Kent and Harlow and Lane because *Tropheryma whippelii* bacterium and the methodology for detecting the antibody are taught by these prior arts. The claimed invention is prima facie obvious over Muller or Schoedon or Drancourt in view of Kent and Harlow and Lane absent any convincing evidence to the contrary.

Applicant argues that Kent and Harlow do not remedy the deficiencies of Muller, Schoedon and Drancourt. In particular, Kent and Harlow and Lane also do not teach or suggest a culture comprising a culture medium and a bacterium responsible for Whipple's disease.

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Applicants' arguments have been fully considered but they are not deemed to be persuasive because the dependent claim stand rejected under 35 U.S.C 102 as discussed above (Muller, Schoedon and Drancourt , primary reference) in view of Kent and Harlow (secondary reference) for teaching a method of diagnosis.

Remarks

8. Claims 1, 10,11, 15, 25 and 29 –32 and 35-42 , 63 and 66-69 are rejected.

Claims 40 and 43-45 are objected as they depend from a rejected claims 1 and 42 respectively.

Relevant Prior Art

9. The prior art made of record and not relied upon in any of the rejections is considered pertinent to Applicants' disclosure:

JAMA, 258; 1039-1043 and *Lancet* 1994, 343(8908):1288) teach strain variation and heterogeneity in diseases cause by *Tropheryma whippelii* .

Clinical and Diagnostic Laboratory Immunology, January 2002, p. 156-159, Vol. 9, No. 1 teaches monoclonal Antibodies to Immunodominant Epitope of *Tropheryma whippelii*.

Relman's (1997(J.I.D. 176: 752-754) teachings indicate *T.Whippelii* is isolated and cultured. He states that no microorganism is uncultivable when one understands the intimate growth requirements of the bacteria.

Pace et al, U.S.Patent 6,083,683 , Pace et al teach a method or in a diagnostic immunoassay kit for the diagnosis of infection (Shigella) in a biological sample (i.e., serum or any other biological fluid) comprising contacting said biological sample with a bacterium or antigen or a fragment thereof having an enhanced antigenic property wherein said bacterium is harvested from a culture and detecting an antibody present in said biological sample binding to the Shigella bacterium or fragment thereof wherein said detecting is by means of an immunoassay ,wherein said immunoassay is a radioimmunoassay, enzyme-linked immunosorbent assay (ELISA,), fluorescent immunoassay, or fluorescence polarization immunoassay (FPIA). The immunoassay or a diagnostic immunoassay used micro titer plates (solid support) for binding bacteria or antigen, and a conjugate antibody. Thus, the art teaches immunoassays for diagnosing bacterial disease associated with bacteria using either bacterium or antigen of said bacterium.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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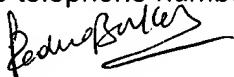
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

11. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Bruce Campell can be reached on (571) 272-0974. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Padma Baskar Ph.D.



BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600